

First Patient Treated in Clinical Trial Testing an Innovative Stem Cell Treatment for HIV/AIDS

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San Francisco, CA – Calimmune has treated the first patient in a clinical trial involving the use of an innovative gene-based stem cell therapy to help protect individuals infected with HIV from the effects of the AIDS virus.

The Phase I/II clinical trial - which California's stem cell agency, the California Institute for Regenerative Medicine (CIRM) is helping fund - focuses on a protein called CCR5 that plays a critical role in enabling HIV to infect cells. Blocking CCR5 may provide the cells a protective shield against HIV, which in turn would help retain immune system functionality

In this study 12 HIV-positive individuals will be infused with their own blood stem cells that carry a gene that has been modified to block production of CCR5. The hope is that those stem cells will then create a new blood system that is resistant to HIV. To guard against the virus forming resistance, the team has used a second mechanism to prevent the virus from fusing with the patient's cells.

"This study is an early but important step in an emerging area of scientific exploration, representing the culmination of more than a decade of research and development," says Calimmune Chief Executive Officer Louis Breton. "We are optimistic that what we learn from this study may bring us closer to the day when a one-time or infrequent treatment could lessen, delay or provide an alternative to a lifetime of antiretroviral therapy."

The goal of the trial – which is being conducted in San Francisco and Los Angeles - is to assess the safety of the therapy, to determine the ease of use and feasibility of the approach for HIV/AIDS patients and to evaluate what, if any, side effects there may be.

"CIRM funding of this Phase I/II trial is an important milestone for us," says Alan Trounson, PhD, President of the stem cell agency. "One of our goals is to support research that moves the most promising science out of the lab and into clinical trials in people. To be able to do that with a disease as devastating as HIV/AIDS highlights the importance of our funding and the potential impact it could have on the health of people around the world."

Jeff Sheehy, the Patient Advocate member of our governing Board for HIV/AIDS, and a longtime community activist, says regardless of the results the trial is important:

"This trial will hopefully offer several important insights into the safety and feasibility of genetically modifying blood forming stem cells in an HIV patient as a potential therapy. We are very early in this research, and with this Phase I trial's goal of establishing safety and the risks involved, I applaud the courage and altruism demonstrated by the patients who are willing to participate in this study."

According to the Centers for Disease Control and Infection (CDC) more than 1.2 million people in the US are living with HIV. This number is growing because new and more effective medications are keeping people alive longer with the infection. However, these medications – which have to be taken every day - are expensive and, over time, have side effects.

For more information about this trial, visit www.clinicaltrials.gov

About CIRM: CIRM was established in November 2004 with the passage of Proposition 71, the California Stem Cell Research and Cures Act. The statewide ballot measure, which provided \$3 billion in funding for stem cell research at California universities and research institutions, was overwhelmingly approved by voters, and called for the establishment of an entity to make grants and provide loans for stem cell research, research facilities, and other vital research.

About Calimmune

Calimmune is a clinical-stage HIV gene medicines company focused on developing innovative cell-based therapies for HIV. The company's stem cell technology was discovered in the labs of Nobel Laureate, Dr. David Baltimore (Caltech) and Dr. Irvin Chen (UCLA AIDS Institute). Calimmune is also developing a rich product candidate pipeline to address the needs of different types of individuals at different states of HIV infection and with different levels of treatment experience.

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